

REMARKS

Claims 1-20 are currently pending in the application after entry of the present amendment. New claims 18-20 have been added. Claim 18 is an independent claim, and claims 19 and 20 depend from claim 18. Support for these amendments is found on page 20, lines 10-12; page 22, lines 3-14; page 23, lines 6-14; Figures 11-12,; and Figures 16-17.

CLAIMS

Claims 1-20 are currently pending in the application. Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. (WO 01/74274) in combination with various other references. Applicants traverse these rejections and respectfully submit that none of the cited references, either alone or in combination, render the claimed invention obvious. Applicants request that the Examiner reconsider and withdraw these rejections in view of the remarks presented herein.

Extensive arguments were presented in the Amendment filed on 31 October 2007. Those arguments will not be reproduced in this Supplemental Amendment.

A. Rejection of Claims 1-4 and 13-15 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al.

As stated in the MPEP:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (MPEP 706.02(j), emphasis added.)

Applicants submit that the Examiner's rejection of claims 1-4 and 13-15 is improper because the Examiner has failed to provide a clear suggestion or motivation that would have led one of ordinary skill in the art to modify the prior art in the manner suggested by the Examiner. The Examiner asserts that "[i]t would be obvious to one of ordinary skill in the art that the use of a plurality of single elements that each form a circle would result in a medical graft having continuous circumferential undulations." The Applicants respectfully disagree. The Examiner specifically states that "Palmaz et al. does not disclose the support arranged specifically as having continuous circumferential undulations."

The Examiner specifically cites the following passage from Palmaz et al.:

In accordance with one of the embodiments of the present invention, there is provided a stent-graft-type device, termed a "web-stent" in which there is at least one of a plurality of structural members that provide a primary means of structural support for the webbed-stent device. The plurality of structural members may be arranged in any manner as is known in the art of stent fabrication, e.g., single element forming a circle or ellipse, a single or plural elements which form a tubular diamond-like or undulating pattern, in which adjacent structural members are spaced apart forming open regions or interstices between adjacent structural members.

Palmaz et al. (WO 01/74274), page 5, lines 13-20, emphasis added.

This passage from Palmaz et al. refers to the structural members of the stent, not to the graft member. In contrast, claim 1 recites a graft "having a plurality of continuous circumferential undulations, with peaks and valleys." Similarly, claim 18 recites a graft "having a plurality of annular ridges forming peaks and valleys." The claimed invention, comprising a graft member, is not analogous to the stent and graft combination referred to in Palmaz et al. and cited by the Examiner.

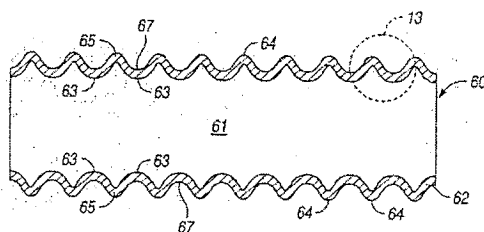
The Examiner cites a passage from Palmaz et al. which states that “structural members may be arranged in any manner as is known in the art.” Yet this passage cannot anticipate the claimed invention because the claimed invention does not even recite a structural member as defined by Palmaz et al. Palmaz et al. makes this distinction clear in the following statement:

Where a graft member is being fabricated, the thickness of the deposited or pre-fabricated starting film may be less than that where a web-stent is being formed, due to the absence of structural members in the graft member.

Palmaz et al. (WO 01/74274), page 6, lines 9-11, emphasis added.

It is clear that the passage in Palmaz et al. relied on by the Examiner regarding structural members is not even applicable or relevant to the grafts of the claimed invention. Palmaz et al. makes it explicitly clear that a graft member is characterized by an absence of structural members.

To further illustrate the differences between Palmaz et al. and the claimed invention, several figures are reproduced below. The first figure illustrates one embodiment of the Applicants' inventive graft as shown in Figure 12 of the pending application.



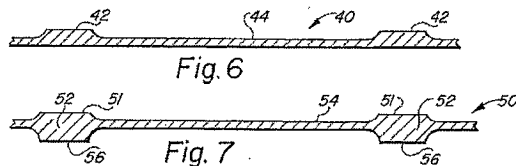
Applicants' graft

Fig. 12

As recited in independent claim 1, the claims are directed to a graft with a “body member having a plurality of continuous circumferential undulations”. Similarly, independent claim 13 recites “a generally cylindrical substrate having a plurality of circumferentially

extending continuous undulations with peaks and valleys, patterned along at least a portion of a longitudinal axis of the generally cylindrical substrate.” The application explains that “[t]he graft body member 62 has first and second wall surfaces forming luminal and abluminal surfaces of the graft body member and a plurality of corrugations or pleats 64 forming an undulating pattern of peaks 65 and valleys 67 in wall surfaces of the graft body member.” (Paragraph [0071].)

In contrast, and as acknowledged by the Examiner, the body member described in Palmaz et al. (illustrated in Figures 6 and 7 of Palmaz et al. and reproduced below) does not include a plurality of continuous circumferential undulations.



Palmaz et al. graft

The Examiner has failed to provide an explanation of how Palmaz et al. could render the claimed invention obvious. Palmaz et al. does not provide each element of the claimed invention. Palmaz et al. does not disclose continuous circumferential undulations, nor does Palmaz et al. disclose a “body member having a plurality of continuous circumferential undulations with peaks and valleys, formed in each of the luminal wall and abluminal wall surfaces of the body member.”

In summary, the Examiner has failed to establish a *prima facie* case of obviousness. Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 103(a) rejection of claims 1-4 and 13-15.

B. Rejection of Claims 5, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al.

Claims 5, 12, and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al. (U.S. Patent No. 6,974,471).

As stated in the MPEP:

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ... If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP § 2143.03, underlining added for emphasis.)

As discussed above, the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claims 1 and 13. Since independent claims 1 and 13 are nonobvious in view of the prior art, all claims depending from independent claims 1 and 13 are also nonobvious. Claims 5 and 12, which depend from independent claim 1, and claim 16, which depends from independent claim 13, are, therefore, also nonobvious.

Additional arguments were presented in the Amendment filed on 31 October 2007. Those arguments will not be reproduced in this Supplemental Amendment.

C. Rejection of Claims 6-10 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Van Schie et al., and further in view of Kula et al.

Claims 6-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al., in view of Van Schie et al., and further in view of Kula et al. (U.S. Patent No. 6,325,825). Since the Examiner has failed to established a *prima facie* case of obviousness with respect to independent claims 1 and 13, all claims depending from independent claims 1 and 13 are also nonobvious. Claims 6-10, which depend from independent claim 1, are, therefore, nonobvious.

Additional arguments were presented in the Amendment filed on 31 October 2007. Those arguments will not be reproduced in this Supplemental Amendment.

D. Rejection of Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Banas et al.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Palmaz et al. in view of Banas et al. (U.S. Patent No. 5,749,880). As discussed above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to independent claim 1. Since independent claim 1 is nonobvious in view of the prior art, claim 11, which depends from independent claim 1, is also nonobvious.

Additional arguments were presented in the Amendment filed on 31 October 2007. Those arguments will not be reproduced in this Supplemental Amendment.

CONCLUSION

Applicants respectfully request that the Examiner withdraw the rejections of claims 1-16 and favorably consider new claims 18-20 based on the remarks presented herein.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

No additional fees are believed to be due for the filing of this Supplemental Amendment. If any fees are due, the Director is hereby authorized to charge any under payment of fees, or credit any overpayment to Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

The Examiner is requested to telephone the undersigned attorney of record if the Examiner believes that there are any outstanding matters capable of resolution by a telephone interview.

Respectfully submitted,



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